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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,430	11/07/2003	Takeo Tanaami	032086	9396

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EXAMINER	
HANNAHER, CONSTANTINE	

ART UNIT	PAPER NUMBER
2884	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,430	TANAAMI ET AL.	
	Examiner	Art Unit	
	Constantine Hannaher	2884	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 07 November 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 20031107.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

It is apparent that the identification of the residence includes neither a state nor a foreign country.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Note the use of "The present invention relates to" which can be implied.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 provides for the use of a power meter, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 2 recites "measuring the detector with the reference light source" but since a source cannot measure the recitation is nonsensical. The claim will otherwise be treated as if it recited "... and then by measuring the reference light source with the detector."

Claims 4 and 5 recite a power measurement instrument dependent upon a detector "calibrated according to the... method" of a parent claim. Process limitations cannot serve to impart patentability to structures. *In re Dike*, 157 USPQ 581, 585 (CCPA 1968). Methods of making a claimed product are immaterial in a product claim in view of *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985) and *In re Brown*, 459 F.2d 531, 173 USPQ 685 (CCPA 1972). It is axiomatic that the additional presence of process limitations, no matter how detailed, cannot impart patentability to a product. *In re Pilkington*, 411 F.2d 1345, 162 USPQ 145 (CCPA 1969); *In re Johnson*, 394 F.2d 591, 157 USPQ 620 (CCPA 1968); and *In re Stephen*, 345 F.2d 1020, 145 USPQ 656 (CCPA 1965). Because a detector calibrated according to the method is indistinguishable from a detector which is not so calibrated (those of ordinary skill in the art have no basis for determining whether any

particular detector has been, in its past, calibrated according to any method) the scope of the claim in indefinite. The intended use of the detector is likewise irrelevant to assessing claim scope.

The balance of the claims is rejected on the basis of their dependence.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 3/1 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made

in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang *et al.* (US20040064053A1).

With respect to independent claim 1, Chang *et al.* suggests a method of calibrating a detector (CCD, Fig. 14) wherein a power meter (photodiode) is used to calibrate the power of each photodetector device of a detector with photodetector device arrays arranged in one dimension or two dimensions and to calibrate the output signals of the detector (paragraph [0094]). In view of the measurement of the values of optical power with traceability to the national standard (NIST traceable calibrated tungsten ribbon filament lamp), it would have been obvious to one of ordinary skill in the art at the time the invention was made that the calibration of the photodiode described was also traceable to a national standard of optical power such that measurement of the spatial distribution of the light source's power by the detector (CCD) was possible directly from the output signals of the detector pixels (since variations in source intensity are corrected with reference to measurements by the photodiode).

With respect to dependent claim 2, the detector (CCD) in the method suggested by Chang *et al.* is calibrated by measuring a reference light source (NIST traceable calibrated tungsten ribbon filament lamp) with the power meter (photodiode) and then by measuring the reference light source with the detector (paragraph [0094]).

With respect to dependent claims 3/1 and 3/2, the detector (CCD) in the method of Chang *et al.* is a camera with a photodetector part comprising a plurality of pixels (paragraph [0091]).

With respect to dependent claims 4/1 and 4/2, the detector (CCD) in the method of Chang *et al.* constitutes a power measurement instrument of the recited type. Tissue, as illustrated in Fig. **14**, constitutes at least "cells."

10. Claims 5/1 and 5/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang *et al.* (US20040064053A1) as applied to claims 1 and 2 above, and further in view of Davis *et al.* (US005620842A).

With respect to dependent claims 5/1 and 5/2, the calibrated fluorescence intensity represented by the output signals of the detector which detects fluorescent power from the fluorescent object in the method of Chang *et al.* is used to classify tissues. Davis *et al.* shows (Fig. **3**) that it is completely well-known to calculate the number of molecules in a fluorescent object from a calibrated detector (flow cytometer, see column 1, lines 9-26). In view of the interest in knowing the number of molecules of a fluorescently labeled antigen on a cell as described by Davis *et al.*, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Chang *et al.* such that it comprised the step of calculating the number of molecules in a fluorescent object from the output signals of the detector (CCD) calibrated according to the suggested method. A power measurement instrument employing the calibrated detector of Chang *et al.* would thus be equipped with a means of calculating as recited.

Response to Submission(s)

11. This application has been published as US20040113096A1 on June 17, 2004 and again as JP 2004-191232 A on July 8, 2004.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nelson *et al.* (US006919919B2) and Staton *et al.* (US006583424B2) both describe methods of detector calibration but may not suggest traceability to a national standard.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Constantine Hannaher whose telephone number is (571) 272-2437. The examiner can normally be reached on Monday-Friday with flexible hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David P. Porta can be reached on (571) 272-2444. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Constantine Hannaher/
Constantine Hannaher
Primary Examiner